1800 M Street, N.W.
Washington, D.C. 20036-5869
202-467-7000
Fax: 202-467-7176

Morgan, Lewis
& Bockius LLP
COUNSELORS AT LAW

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VIA FEDERAL EXPRESS

Dockets Management Branch
Food and Drug Administration, HFA - 305
Department of Health and Human Services
Room 1061
5630 Fishers Lane
Rockville, MD 20857

Re: **PETITION FOR STAY OF AGENCY ACTION**

Dear Madam or Sir:

The undersigned submits this Petition on behalf of Playtex Products, Inc. ("Playtex"), under 21 C.F.R. § 10.35, requesting that the Commissioner of Food and Drugs stay the effective date of any pending, tentative, or final decision to exempt make-up, moisturizer or other products used on the face that include sunscreen ingredients from the Food and Drug Administration's ("FDA's") over-the-counter ("OTC") and sunscreen drug labeling regulations. 21 C.F.R. §§ 201.66 & 352.52. This request is made pursuant to sections 201 (g)(1) and 502 of the Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. §§ 321 (g)(1); 352, and section 10 (e) of the Administrative Procedure Act ("the APA"), 5 U.S.C. §§ 706 (2)(A); 706(2)(C).

I. Decision Involved

The decision as to which Playtex seeks a stay is any pending, tentative or final decision by FDA to grant, in response to a request for such an exemption by the Cosmetic, Toiletry, and Fragrance Association ("CTFA") ("the CTFA exemption"), an exemption for combination sunscreen and cosmetic products used on the face ("sunscreen face products") from the OTC and sunscreen

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drug labeling regulations.[1/] 21 C.F.R. §§ 201.66; 352.52. Specifically, Playtex requests that, for purposes of enforcing the OTC and sunscreen drug labeling requirements, the Agency refrain from distinguishing between sunscreen products that are used to protect the face and other parts of the body from exposure to harmful ultraviolet ("UV") rays ("sunscreen products") and sunscreen face products. Playtex requests the Agency to apply the OTC and sunscreen drug labeling requirements uniformly to all products that include sunscreen drug ingredients. Further, Playtex requests that the Agency stay the effective date of the OTC and sunscreen drug labeling requirements[2/] for all sunscreen drug products pending resolution of these issues.

II. Action Requested

Playtex requests that FDA promptly stay any pending, tentative, or final decision to grant an exemption for sunscreen face products from the OTC and sunscreen drug labeling requirements. In addition, Playtex requests the Agency to stay the effective date of any labeling requirements as they apply to any product that includes sunscreen ingredients pending resolution of these issues.

III. Statement of Grounds

A. Background: FDA's Monograph and Labeling Regulations for OTC Sunscreen Products

1. FDA's Monograph for OTC Sunscreen Products

In 1993, FDA published a notice of proposed rulemaking (the "tentative final monograph" or "TFM") for OTC sunscreen drug products. 58 Fed. Reg. 28,194 (May 12, 1993). The TFM proposed conditions under which OTC sunscreen drug products are generally-recognized-as-safe and-effective ("GRAS/E") under section 201(p) of the Act and not misbranded under section 502 of the Act. 21 U.S.C. §§ 321(p); 352. Following extensive modifications to the proposed TFM, FDA finalized the sunscreen monograph on May 21, 1999. 64 Fed. Reg. 27,666 (May 21, 1999).

1/ We understand that FDA is considering granting an exemption for sunscreen face products based on a meeting between CTFA representatives and FDA. If FDA is considering such an exemption, it would represent a significant change to the monograph and therefore, under the APA, must be subject to rulemaking to ensure that the public is given proper notice and the opportunity to comment on the exemption.

2/ 21 C.F.R. §§ 201.66; 352.52.

As published, the final monograph essentially completes the TFM[3/] and finalizes certain labeling requirements for sunscreen drug products. Id. (codified at 21 C.F.R. Part 352). The sunscreen monograph labeling requirements, which are supplemented by FDA's more general OTC drug labeling rule,[4/] are intended to ensure that consumers can read and understand sunscreen product labels and are adequately protected from the sun.[5/] 64 Fed. Reg. 27,666, 27,673 (May 21, 1999).

2. FDA's Final OTC Drug Labeling Rule

FDA also recognized the fundamental importance of eliminating consumer confusion and ensuring that consumers receive uniform, accurate, and coherent information about the proper use of sunscreen products in its more general OTC drug labeling regulation.[6/] 64 Fed. Reg. 13,254 (March 17, 1999). Thus, the OTC drug labeling regulation requires all OTC drug products, including most sunscreen products, to include a list of active ingredients and their purposes under the title, "Drug Facts" in their product labels, as well as other product information intended to ensure the safe and effective use of such products. 64 Fed. Reg. 13,254, 13,269 (March 17, 1999) (stating that the Agency believes that the new labeling format that is

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3/ The final monograph does not address certain testing issues and UVA exposure labeling requirements. These issues will be addressed in a future regulation. 64 Fed. Reg. 27,666 (May 21, 1999).

4/ 21 C.F.R. § 201.66.

5/ FDA has imposed these labeling requirements on sunscreen products pursuant to section 502 of the FFDCA which requires that all drug products bear labeling that is "likely to be read and understood by the ordinary individual under customary conditions of purchase and use." 21 U.S.C. § 352 (c).

6/ The OTC drug labeling regulation imposes general labeling requirements on all OTC drug products ("OTC drug labeling regulation") and, thus, applies to sunscreen products. To the extent that a specific sunscreen monograph or regulation does not specifically provide otherwise, sunscreen products must comply with the general OTC drug labeling regulations. 64 Fed. Reg. 13,254 (March 17, 1999); 21 C.F.R. § 201.66. The OTC drug labeling regulation establishes a standardized format for the labeling of all OTC drug products. Among other requirements, the rule requires product labels of OTC drug products, including most sunscreen products, to include standardized headings such as drug facts, certain warning statements, and to use larger font and type size on the label. See 64 Fed. Reg. 13,254 (March 17, 1999); 21 C.F.R. § 201 et. al.

required under the OTC drug labeling rule "will improve consumer understanding of the names and purposes of active drug ingredients, including those typically used in sunscreens").

Recognizing the importance of providing uniform information to consumers about OTC sunscreen drug products, therefore, FDA specifically stated in both the preamble to the final sunscreen monograph and the preamble to the OTC drug labeling regulation that products that include ingredients that are marketed for their sunscreen properties are drugs subject to the OTC and sunscreen drug labeling requirements. 64 Fed. Reg. 27,666 (May 21, 1999); 64 Fed. Reg. 13,254, 13,269 (March 17, 1999). Playtex expects that, consistent with this view and its public health mandate, FDA will apply these requirements uniformly, because there is no legal or scientific basis for distinguishing sunscreen products used on the face from sunscreen products used on other parts of the body, for the reasons set forth below. Therefore, no labeling exemptions should be granted for subproduct categories of sunscreens.

B. FDA Does Not Have the Statutory Authority to Exempt Sunscreen Face Products From the OTC and Sunscreen Drug Labeling Requirements

An exemption for sunscreen face products will contravene the FFDCA because it will improperly exclude these products from regulation as drug products, result in consumer confusion about the safe and effective use of sunscreen products, and adversely affect the public health. Under section 201(g)(1) of the FFDCA, any product that is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease is subject to regulation as a drug. 21 U.S.C. § 321 (g)(1). Consistent with the statute, FDA has a long-established policy that any combination drug/cosmetic product that includes a sunscreen ingredient to mitigate or prevent the harmful effects of UV light on the skin is subject to regulation as a drug product. See 58 Fed. Reg. 28,194 (May 12, 1993) (stating that "regardless of the claims, products intended to be used for the prevention of sunburn or any other similar condition should be regarded as drugs"); see also Warning Letter from Douglas Tolan, District Director, Food and Drug Administration to Charles Hsiao, President, Baker Cumins Pharmaceuticals, Inc. (Feb. 18, 1992) (stating that the company's product, "therapeutic aquaderm SPF 15 Face Cream" is a drug because the manufacturer makes claims that the product protects against harmful skin-aging rays of the sun and identifies sunscreen ingredients in the product label); Letter from Douglas Tolan, District Director, Food and Drug Administration to Gary DeAngelo, President, Sun & Skincare, Inc. (April 9, 1996) (stating that sunscreens are drugs because of their claims to provide minimal protection from the harmful rays of the sun). The Agency has stated most recently that:

> The basis for the agency's determination that products intended for use as sunscreens are subject to regulation as drugs under section 201(g)(1) of the

> Federal Food, Drug, and Cosmetic Act . . . is [that] sunscreen active ingredients affect the structure and function of the body by absorbing, reflecting, or scattering the harmful, burning rays of the sun, thereby altering the normal physiological response to solar radiation. Proper use of sunscreen ingredients . . . may help to prevent skin damage and may help reduce the risk of skin lesions, skin cancer, and other disease conditions. Products that are marketed to achieve these important health benefits meet the definition of 201 (g)(1)(B) and (g)(1)(C) of the act. 64 Fed. Reg. 27,666, 27,668 (May 21, 1999).[7/]

Under a proper statutory construction of the FFDCA and the Agency's interpretation of the Act, therefore, a product that includes a sunscreen ingredient and includes labeling claims regarding its sunscreen properties (such as reference to SPF protection or other similar statements) is intended as a drug and subject to FDA's drug regulations. For purposes of the drug regulatory framework under the FFDCA, it is inconsequential that a product offers sunscreen protection as an additional or even secondary purpose or that its labeling includes only a single statement identifying the SPF value of the product; it is nonetheless a drug, subject to FDA's sunscreen drug regulations. In its final rule regarding OTC sunscreen products, FDA explicitly rejected the argument that a product that offers sunscreen protection as a secondary feature is exempt from regulation as a drug product.[8/] The Agency stated:

> The idea that sunburn protection is offered by the product as only a "secondary" feature for a consumer is not relevant. If an intended use of the product is to provide users with sun protection when they go outside, then the product is subject to regulation as a drug. 64 Fed. Reg. 27,666, 27,669 (May 21, 1999).

Further, it is well established that cosmetic products that include sunscreen ingredients are not exempt from regulation as a drug even if the product label only identifies the SPF value of a sunscreen ingredient. As the Agency stated in the preamble to the TFM for sunscreen products,

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7/ See also 58 Fed. Reg. 28,194, 28,203-28,206 (May 12, 1993) (also setting forth the basis for the Agency's determination that products intended for use as sunscreens are subject to drug regulations).

8/ FDA has rejected other claims that combination cosmetic/drug products are exempt from from the OTC labeling regulations because they offer therapeutic benefits as a secondary feature. 64 Fed. Reg. 13,254, 13,269 (March 17, 1999) (stating that antidandruff shampoos, anticaries toothpaste, and antiperspirants are subject to regulation as drug products).

the use of terms such as "SPF," or the use of any SPF value in the product labeling is a basis to regulate the product as a drug because the SPF value provides assurance to consumers that it will protect skin from sun damage and prevent skin disease. See 58 Fed. Reg. 28,194 (May 12, 1993). Any sunscreen face product that includes a statement on the label regarding SPF levels, or that otherwise calls attention to the inclusion of sunscreen ingredients, therefore, is subject to the same OTC drug and sunscreen labeling requirements.[9/]

FDA's insistence on the need to treat these products as drugs is premised on the serious adverse health effects resulting from sun exposure. As stated in the preamble to the final monograph for OTC sunscreen products:

> [R]egardless of what type of product a consumer chooses for sun protection, the essential information relevant to sun protection is the same. Thus, to ensure that consumers are adequately protected from overexposure to the sun, all products intended for use as sunscreens should have similar labeling requirements, irrespective of their method of use and irrespective of whether the sunscreen use is considered secondary or primary. 64 Fed. Reg. 27,666, 27,673 (May 21, 1999).

In fact, they may be using this product as their primary form of protection. Moreover, it is clear that many consumers specifically choose to purchase sunscreen face products generally at a higher price than non-sunscreen cosmetics because they contain sunscreen drug properties and offer UVA and UVB protection.[10/] Without proper sunscreen labeling, however, consumers may

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9/ The Agency has stated that products that do not make express or implied sun protection claims and that do not contain sunscreen ingredients may be regarded as cosmetics under the act. 64 Fed. Reg. 27,666, 27,669 (May 21, 1999). FDA also has stated that if a product is "intended solely to provide cosmetic effects on the skin (e.g., to moisturize the skin while sunbathing)" the product may be marketed as a cosmetic rather than a drug. Id. (emphasis added). Under this analysis, make-up products that include sunscreen ingredients and that bear a statement regarding SPF protection cannot qualify for cosmetic status because they make sun protection claims and include sunscreen ingredients. Consequently, there is no basis to deem such products solely cosmetics and to exempt them from the drug labeling rules for sunscreen products.

10/ See e.g., "Do I Look Older . . .The Generation Is Now Chasing the Fountain of Youth with 'Cosmeceuticals,'" Los Angeles Times (Jan. 21, 2000) (noting purchase by millions of consumers of hybrid cosmetics and pharmaceuticals, including combination

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improperly select or use these face sunscreen products, thus reducing the effectiveness of these drugs.[11/] For instance, consumers may fail to use a sunscreen that offers an appropriate level of UV protection for them, fail to reapply the product to the face as needed, use products that are incompatible with or eliminate the efficacy of the sunscreen ingredient, or not understand that use of the sunscreen is but one step in a total sunscreen protection program. As the Agency has repeatedly recognized, therefore, it is critical that consumers receive uniform accurate information and directions regarding the proper use, safety, and efficacy of all sunscreen products and are not confused by arbitrary distinctions between the labeling requirements for sunscreen face products and other sunscreen products. 64 Fed. Reg. 13,254, 13,269 (March 17, 1999) (expressing Agency concern that consumers will be unnecessarily confused if FDA were to allow cosmetic/sunscreen drug products, such as moisturizers, to bear markedly different labeling than other standard sunscreen products). Consequently, FDA must require sunscreen face products to meet the same sunscreen drug labeling regulation standards as other products that contain sunscreen ingredients. Any product does that does not conform to these standards is misbranded and, thus, unlawful. More importantly, however, such products may compromise the short and long-term health of consumers.

Permitting sunscreen face products to evade the labeling requirements that apply to other sunscreen products will compromise the ability of consumers to select and use sunscreens safely

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sunscreen/cosmetic products); see also "Tick Tock: The Clock Stops For No One, But, New Ingredients, Formulas, Products and Technology Claims To Aid In The Ultimate Aging Of Skin," Global Cosmetic Industry (July 1, 2000) (noting that there is a "major thrust for skin-care products to include sunscreen" and an increased demand for sunscreens that block UVA and UVB rays); "U.S. Cosmetics and Toiletries Sector in 1995: Part II," Drug and Cosmetic Industry (June 1996) (noting that consumers are willing to purchase combination drug/cosmetic products at higher prices due to the perceived health benefits of these products).

11/ See e.g., "A New Approach to Sun Care," Soap and Cosmetics (May 1, 2000) (discussing consumer confusion about the different degrees of protection different SPF levels offer and consumer confusion about the proper use of sunscreen products and that "people don't realize that when a product is waterproof, it does not mean it's 'towelproof.' While a lotion or spray may stay on during a swim, consumers wipe their faces with a towel, the product is no longer effective and needs to be reapplied").

and effectively.[12/] FDA has previously found that similar products labeled differently results in consumer confusion. Thus, to eliminate consumer confusion and ensure safe and effective use of all sunscreen products, FDA should deny any request for an exemption for any subproduct category of sunscreen products.[13/]

Moreover, there is no basis to grant an exemption for sunscreen face products. FDA has stated that it will grant a limited exemption for sunscreen products that: (1) are labeled for use on specific small areas of the face (e.g., lips, nose, ears, and/or around the eyes); and (2) meet FDA's small packaging requirements under 21 C.F.R. § 201.66.[14/] 21 C.F.R. § 352.52 (f). This limited exemption, however, is inapplicable to sunscreen face products, which likely will not meet FDA's definition of small package products, and are not intended for application only on

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12/ See e.g., 62 Fed. Reg. 9,024, 9,027-9,028 (Feb. 27, 1997) (discussing consumer confusion and adverse health risks due to differences in OTC drug labels, changing patterns of OTC drug use, and the potential for adverse drug reaction and misuse of OTC drug products and citing Holt, G.A. et. al., "OTC Labels: Can Consumers Read and Understand Them?" American Pharmacy, NS30:51-54, 1989; Lumpkin, J.R. et. al., "A Shopping Orientation Based Prescription for the Treatment of OTC Medication Misuse Among the Elderly," Health Marketing Quarterly 8:95-118, 1990).

13/ FDA has explicitly recognized the need for uniform sunscreen labels "to ensure consumers are adequately protected from overexposure from the sun, all products intended for use as sunscreens should have similar labeling requirements . . . irrespective of whether sunscreen use is considered primary or secondary to the product." 64 Fed. Reg. 27,666, 27,673 (May 21, 1999).

14/ Under 21 C.F.R. § 201.66, a product package is considered "small" if more than 60 percent of the total surface area available to bear labeling on the entire outside container or wrapper, or the immediate container label if there is no outside container or wrapper, would be needed to present FDA's required labeling. If a product meets these standards, the product is permitted to apply certain modifications and, thus the labeling will differ from that normally required of other OTC drug products. The labeling normally required of other OTC drug products includes drug facts, uses, warnings, as well as other information. 21 C.F.R. § 201.66 (d)(10); see also 64 Fed. Reg. 27,666, 27,681- 27,682 (May 21, 1999).

small parts of the face like the nose and around the eyes.[15/] Consequently, FDA cannot exempt sunscreen face products under the exemption for small parts of the face.

Similarly, there also is no rational or scientific basis to distinguish sunscreen face products from other sunscreen products intended for other parts of the body that are subject to the OTC drug and sunscreen labeling regulations. Thus, if FDA grants an exemption for face sunscreen products, it must grant an exemption for other sunscreen products that are intended for use on other parts of the body. Like other sunscreen products, face sunscreen products are intended to be used on large areas of the face like the neck, ears, and possibly head and forehead. Nor are their sunscreen properties viewed or used incidentally. Unlike sunscreen products that are intended only for use on limited areas of the face like around the eyes, consumers often rely solely on sunscreen face products to provide facial sunscreen protection. Accordingly, sunscreen face products are not distinguishable from other sunscreen products that are intended for use on other parts of the body and FDA cannot grant an exemption for sunscreen face products from the OTC drug and sunscreen labeling requirements without extending it to other sunscreen products.

In addition, if FDA grants an arbitrary exemption to one subcategory of sunscreen products, a number of manufacturers of other OTC products will maintain that they are eligible for similar exemptions on grounds that these products are also sold in packages that are too small to accommodate the required labeling information and/or are intended only for use on limited areas of the body, e.g., underarms, scalp, and teeth, and/or are used for both drug and cosmetic purposes. Such an iniative would be inconsistent with the Agency's mandate to provide rational, uniform regulation of OTC drug products. Playtex, therefore, urges FDA to refrain from granting an arbitrary exemption to sunscreen face products from the OTC and sunscreen labeling regulations.

15/ FDA has stated that to qualify for an exemption from the OTC drug and sunscreen labeling regulations, the product must: (1) typically be packaged in small amounts; (2) have a high therapeutic index; (3) have an extremely low risk when used by consumers; (4) provide a favorable public health benefit; (5) have no specified dosage limitation; (6) require few specific warnings and no general warnings. See 64 Fed. Reg. 13,254, 13,270 (March 17, 1999). In addition, the product must have: (1) a [limited] intended use; (2) have a high overall safety profile; and (3) a limited area of application. 64 Fed. Reg. 27,666, 27,682 (May 21, 1999).

C. It Would Be Arbitrary and Capricious to Grant Certain Sunscreen Face Products An Exemption From FDA's Sunscreen Labeling Requirements

Because there is no statutory basis to treat similarly-situated sunscreen face and sunscreen drug products differently, it would be arbitrary and capricious and in excess of the Agency's statutory authority under the APA, 5 U.S.C. §§ 706(2)(A), 706(2)(C) for FDA to exempt face products that include sunscreen ingredients from the sunscreen labeling requirements.

The APA expressly provides that a reviewing court shall "hold unlawful and set aside agency actions, findings, and conclusions found to be -- (A) arbitrary and capricious, an abuse of discretion or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). In determining whether an agency's actions are arbitrary and capricious under the APA, the courts have held that the principal inquiry is whether an agency's action constitutes "reasoned decisionmaking."[16/] Lack of reasoned decisionmaking is evidenced by: (1) no record support for factual findings; (2) decisions contrary to facts in the record; (3) failure to disclose reasons for decisions; and (4) misunderstanding of the law.

Under the FFDCA, there is no statutory basis to distinguish between these sunscreen face products and other sunscreen products. Both kinds of products include ingredients that are intended to mitigate or prevent the harmful effects of UV light and are specifically marketed for this purpose. From a medical perspective, the face is as important, if not more important, to protect from UV light as other body sites. The need for accurate information about the proper use of sunscreen products is particularly heightened in the case of sunscreen face products because studies have shown that there is an increased risk of skin cancer in certain body sites such the face that are chronically exposed to the sun.[17/] These cancers are more commonly

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16/ See American Lung Ass'n v. EPA, 134 F.3d 388, 392 (D.C. Cir. 1998) ("we have always required the Administrator to 'cogently explain why [she] has exercised [her] discretion in a given manner'") (quoting Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 48 (1983)); cf. General Elec. Co. v. United States Dep't of Commerce, 128 F.3d 767, 774 (D.C. Cir. 1997) (by failing to explain changes from a proposed rule, the agency "failed to exercise reasoned decisionmaking"); Milk Indus. Found. v. Glickman, 967 F. Supp. 564, 570 (D.D.C. 1997) (reasoned decisionmaking precludes "a '[s]udden and unexplained change'") (quoting Smiley v. Citibank, 517 U.S. 735, 742 (1996)).

17/ See Buettner, P.; Raasch B., Incidence Rates of Skin Cancer in Townsville, Australia, Int. (continued...)

squamous and basal cell carcinomas but malignant melanomas also occur. One study showed, for example, that carcinoma may develop in the face due to chronic solar exposure and damage.[18/] Consequently, it is vital that consumers have accurate and uniform information about sunscreen face products, and that consumers are not confused by arbitrary distinctions between sunscreen face products and other sunscreen products. Moreover, many sunscreen face products contain the same level of SPF as sunscreens intended for use on all parts of the body. Consumers purchase face sunscreens due to the therapeutic benefits offered by such products and forego use of other sunscreens, i.e., they use face sunscreens as their primary form of protection. Thus, like other sunscreen products, face products that include sunscreen ingredients are drug products and subject to FDA's drug regulations. To regulate these products differently would be arbitrary and therefore unlawful.

The courts have expressly held that the disparate treatment of two similar products that share the same important characteristics is arbitrary, capricious, and a violation of administrative law. In Bracco Diagnostics, Inc. v. Shalala, for example, the court rejected FDA's decision to regulate one injectable microbubble ultrasound imaging agent as a drug and another, virtually identical, product as a device. The court stated that "the disparate treatment of functionally indistinguishable products is the essence of the meaning of arbitrary and capricious." 963 F. Supp. 20, 24 (D.D.C. 1997) (citing National Association of Broadcasters v. FCC, 740 F.2d 1190, 1260 (D.C. Cir. 1984); Doubleday Broadcasting Co. v. FCC, 655 F.2d 417, 423 (D.C. Cir. 1981)). Under Bracco, there is no basis to discriminate between sunscreen products that are used on the face and sunscreen products that are used on other parts of the body. Both are offered and marketed for their protective properties from the harmful effects that can result from overexposure to UV rays and thus, share similar important characteristics. The fact that face

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J. Cancer, 1998, 78(5); 587-93 (concluding that site-specific incidence rates of non-melanocytic skin cancer were extreme on sun-exposed areas of the face and that less exposed body sites, such as unexposed upper limbs or thighs, showed reduced incident rates for all types of skin cancer); see also Koscard, E., Solar Keratoses and Their Relationship to non-Melanoma Skin Cancers, Australas J. Dermoidal., 1997, 38 Supp. 1:S30 (concluding that basal cell carcinoma may develop in a soft type of solar keratoses, particularly in the face, which may result from chronic solar exposure and damage). Ellwood, JM, Gallagher RP, Body Site Distribution of Cutaneous Malignant Melanoma in Relationship to Pattern of Sun Exposure, Intl. Journal of Cancer, 1998; 78; 276-280.

18/ See Buettner, P.; Raasch B., Incidence Rates of Skin Cancer in Townsville, Australia, Int. J. Cancer, 1998, 78(5); 587-93.

products also offer cosmetic benefits does not affect whether such products are also subject to regulation as a drug. Consequently, consistent with the APA, if FDA imposes OTC and sunscreen drug labeling requirements on sunscreen products to ensure the protection of public health, it cannot arbitrarily engage in the disparate treatment of some sunscreen products, without violating the APA and injuring consumers.

D. FDA Must Stay Any Pending, Tentative, or Final Decision to Exempt Certain Face Products from Sunscreen Drug Labeling Regulations in the Interest of Public Health

It is well-established that excessive exposure to UV radiation can result in several adverse health conditions. These health conditions include immediate sunburn, premature aging, wrinkles, other skin damage, and skin cancer, including basal cell carcinoma, squamous cell carcinoma, and malignant melanoma. Due to these potential adverse and potentially deadly health consequences, it is critical that consumers recognize the importance of using sunscreen, understand how to use sunscreen properly, and have access to uniform, clear, and accurate information that does not create consumer confusion about sunscreen products.

The significance of uniform labeling requirements for sunscreen products can only be appreciated in the context of FDA's discussions regarding the importance of providing consumers with clear and accurate information regarding all OTC products, including sunscreen products, so that consumers can safely and effectively use OTC products. In that context, FDA has unequivocally maintained that the provision of essential information in a uniform format to consumers about the proper usage of sunscreen is critical to ensure that all consumers are adequately protected from overexposure to the sun. 64 Fed. Reg. 13,254, 13,268-13,269 (March 17, 1999).

Public health interests will not be served, however, if FDA exempts face products that include sunscreen ingredients from the sunscreen labeling regulations. The health concerns about overexposure to UV light are no less serious if they result from facial exposure rather than other points of contact with harmful rays from the sun. The face, for example, is frequently a site of basal and squamous cell carcinomas,[19/] and also lentigo maligna. Moreover, melanomas occur

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19/ See Puizina-Ivic N., Matokovic B., Gluncic I., Maslovara S., Vela-Ljubic J., Histopathologic Variants of Basal Cell Carcinoma Correlation with Sex, Age and Localization, Journal of Medical Systems, 1999;23:389-400; Jackson R., Geographic

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more frequently on the face and forearms than other parts of the body. Thus, there are significant health risks associated with facial exposure to the sun. As previously stated, in comparison to other areas of the body, the face is chronically exposed to UV light more than any other part of the body. As a result, proper use of facial sunscreen products is just as important, if not more important, to the public health as the proper use of sunscreen products that are intended for use on other parts of the body. In many cases, consumers rely on facial products that bear statements regarding sunscreen ingredients, e.g., "SPF 15," as the sole source of a facial skin protectant from the harmful UV light. To the extent that consumers rely on facial products that include sunscreen ingredients to provide protection from the harmful rays of the sun, therefore, proper usage of and information regarding such products is critical to the public health. If not informed through appropriate labeling of the proper usage of these sunscreen products, however, consumers will improperly rely on these products which may result in overexposure to sunlight and the health complications that can arise from such excessive exposure to UV rays. Consequently, FDA should stay any decision to exempt facial products that include sunscreen ingredients from the sunscreen labeling regulations.

IV. Playtex Will Suffer Irreparable Injury if the Stay Is Not Granted

The failure of FDA to grant the stay requested in this Petition will result in irreparable injury to Playtex. If the Agency grants an exemption for sunscreen face products that contain sunscreen ingredients, the disparity in labeling for sunscreen products will confuse consumers and convey a message to consumers that proper usage of sunscreen products intended for facial application is not essential to health. Consequently, Playtex will be irreparably injured if the stay is not granted despite its significant efforts to provide products that protect consumers from overexposure to UV radiation from the sun.

19/(...continued)

Pathology of Skin Cancer, Journal of Cutaneous Medicine & Surgery, 1999;3:120-2; Hannoksela, Svahn A, Pukkala E.; Karvonen J., Basal Cell Carcinoma and Other Nonmelanoma Skin Cancers in Finland from 1956 through 1995, Arch. Dermatol. 1999 Jul.; 135(7):781-6 (finding an increasing incidence of basal cell carcinoma and nonmelanoma skin cancers in the face, scalp, and neck in the population studied); Leber K., Perron VD, Sinni-McKeehen B., Common Skin Cancers in the United States: A Practical Guide for Diagnosis and Treatment, Nurse Practitioner Forum, 1999;10:106-12.

V. Playtex's Case Is Not Frivolous and Is Being Pursued in Good Faith

Since the Agency published the tentative final monograph, Playtex has actively participated in development of appropriate testing, compositional and labeling standards for sunscreen ingredients that protect consumers against harmful UV radiation in an effort to ensure that the public has access to and understands how to properly use sunscreen products that will protect against UV radiation. FDA has acknowledged the importance of ensuring that consumers properly comprehend how to use all products that include sunscreen ingredients. If some products that include sunscreen ingredients are regulated differently from other products that include sunscreen, however, consumer confusion will result. Moreover, consumers will not properly use sunscreen face products resulting in adverse health risks. FDA has conceded that the public health will be best served by properly labeled sunscreen products to ensure maximum protection from harmful exposure to UV radiation. Consequently, Playtex's case is not frivolous and is being pursued in good faith.

VI. There Are Sound Public Policy Grounds Supporting the Stay

There are sound public policy grounds for the FDA to grant the stay that Playtex requests in this Petition. First, the disparate treatment of facial products that include sunscreen ingredients and other sunscreen products will confuse the public about the protective efficacy of sunscreen products and thus, may discourage certain consumers from properly using sunscreen effectively. Secondly, an exemption for facial products that include sunscreen ingredients from the labeling requirements could encourage consumers to remain in the sun for longer periods of time, increasing the exposure to harmful UV radiation. As such, the exemption will harm rather than protect the public health.

VII. Conclusion

Playtex respectfully requests that, for the above described reasons, and as mandated by the FFDCA and the FDA's implementing regulations, the FDA promptly stay any pending, tentative, or final decision to exempt sunscreen face products that include sunscreen ingredients from the sunscreen labeling regulations.

Respectfully submitted,

Kathleen M. Sanzo

Kathleen M. Sanzo
Counsel for Playtex Products, Inc.

cc: Paul Yestrumskas, Esq.
Playtex Products, Inc.

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HEADLINE: A New Approach to Sun Care.

BYLINE: PLACE, JENNIFER

BODY:

A new generation of sun care products makes running for the shade no longer the only alternative to having dry, sun-damaged skin and hair

While **skin** and hair **care** products with the added benefit of a **sunscreen** have been on the market for some time, new offerings in sun **care** are beginning to include **skin** and hair **care** ingredients. As a result, consumers are being offered new "hybrid" products that offer better sun **protection** than a product with an added **sunscreen,** while at the same time adding moisturization and anti-aging properties.

Gregory Dean, product and spa consultant, Institut Esthederm points out that "There is a focus on making [sun **care**] more of a **skin care** product rather than just something you're going to lay out in the sun with. Fortunately for us, our company has been very much a part of creating this trend and our sun tan line has been one that has been a **skin care** product from the beginning -- we never really were just a sunblock."

Institut Esthederm's product range includes Optimum Bronzage Optimum Tanning Suncare Cream, a product that features a compound of pure active vegetable ingredients, vitamin E and mineral particles that leave the skin soft and help fight free radicals that cause premature aging. This product is also formulated with Adaptaline 200, a complex that contains tyrosine, a melanin precursor, that stimulates the skin's own production of melanin creating a faster, safer and longer-lasting tan. Recognizing that people will always want to have a healthy brown glow, "what we try to do is work with the skin the way it naturally tans," Dean says. "We speed up that tanning process so that it takes less sun exposure to get the maximum amount of tanning. This is what the Adaptaline does. It triggers, stimulates and reinforces the tanning process under low UV exposure and takes away the skin's sensitivity to light." Dean explains that when the skin is exposed to the sun, melanin is produced, which begins the tanning process. M ost of the time, for anyone who is fair skinned, their skin has already begun to burn by this point. With the use of this product, though, the tan is achieved faster, giving the skin its own defense against burning.

With beautifully tanned bodies making a comeback on magazine pages, television and in the movies, this approach to sun care is more realistic than telling the public to avoid the sun altogether, Another option to achieve the tan of the islands is to use self-tanners, a category that continues to show exceptional growth. Nancy Arbelo, marketing consultant; Sothys, notes that Sothys sun care line has exceeded expected profits by 30 percent and she attributes this increase mostly to the self-tanning segment.

Like the products offered by Institut Esthederm, Sothys' offerings give more than just UV protection or a tan appearance. "Our self-tanner is not just a self-tanning product. It has an ingredient called Photonil, which helps protect the langer cells, prevents hyperpigmentation and also protects against free radicals and the skin from dehydration," tells Arbelo.

To its sun care line, the company has added liquid crystals that help the active ingredients penetrate the skin. "Liquid crystals have the same actual development as the lipids in our skin, so it's able to penetrate and deliver the active ingredients of the product. It also hydrates the skin," Arbelo explains. The company's Creme Haute Protection (High Protection Cream) also contains Photonil, and offers an SPF of 15. In addition, it contains shea butter for smoothing, Filagrinol for hydration and gingko biloba to deliver a high dose of antioxidants that counteract the dangerous effects of sun-stimulated free radicals.

A QUICK AND EASY APPLICATION

Not only are consumers looking for better sun protection in a multi-beneficial formulation, they are seeking more convenient ways of applying these products as well. This growing interest in ease-of-use has given rise to the popularity of sprayable formulations. "People tend to find sprays more convenient to use," Julie Kofman, spokesperson, L'Oreal says. "Men definitely prefer sprays to lotions and kids think it's more fun. We do offer lotions in our line, but we're really focusing on sprays -- they are more kid- and male-friendly."

Two new sprayable formulations that L'Oreal is introducing this season are Ombrelle Sunless Spray SPF 12 and Ombrelle Sunscreen Spray for Kids SPF 28. Both offer broad-spectrum protection with Parsol 1789 as the active ingredient and include vitamin E. The kids' product also contains sunflower seed oil for extra softening benefits.

Stephanie Mellenberndt, product manager, Hawaiian Tropic, also emphasizes the increased consumer interest in sprays. For the 2000 summer season, Hawaiian Tropic has responded to this trend by introducing two new sprays: Tan Amplifier Carrot Oil, a line extension to the company's successful Tan Amplifier brand, and [Tan.sub.2] Max Indoor Tanning Spray, which is specially formulated for salon tanning.

Also introducing an SPF 12 spray this season is Shiseido. Its Refreshing Protective Spray SPF 12 is formulated with Parsol 1789 for UVA and UVB protection; Parsol 13, or Octyl Methoxicinnamate, a UVB blocker; scutellaria root extract, which reinforces skin integrity by helping to prevent the formation of lipid peroxides; EPCK, a combination of vitamins C and E; white

lily extract, which moisturizes the skin and protects against oxidation; and macademia nut oil to energize skin.

Lorraine Wilner, executive director, Shiseido Studio, says that "people are concerned not only with protection from the sun, but also want the products to have treatment benefits, not to mention ease of application." Taking convenience one step further, Refreshing Protective Spray was designed for the hair as well as the skin -- one product leaves the wearer protected from head to toe.

Formulated especially for the hair, Ales Group's Phytoplage Protective Sun Veil is launching next month at select department stores and fine salons. To be sprayed on the hair both before and during prolonged sun exposure, Phytoplage Protective Sun Veil contains sweet almond extract to seal and soften the hair, sunflower extract to strengthen the hair's natural resistance by preventing the production of free radicals and a UV filter. While this is the latest sun protection for the hair that Ales Group offers in its Phytoplage line, there are a number of other existing products. "Apart from sun protection, consumers are looking for sun care products that cleanse the hair after salt and chlorine exposure, such as our Phytoplage Sun Shampoo, as well as repair it, like Phytoplage after-sun repair does," explains a spokesperson for Ales Group. "Some people like sun care products to enhance their hair style, like Phytoplage Oil," he continues.

KNOWLEDGE IS KEY

Although consumers finally seem to understand the importance of protecting themselves from UV light, there is still some confusion about how much protection an SPF of 15 offers as compared to an SPF 45 product, and what it really means when a product is labeled "waterproof."

Institut Esthederm's Dean believes that SPF numbers are very misleading for consumers and eventually the Food and Drug Administration (FDA) will do away with SPF numbers entirely. "We saw in the past couple of years, when the FDA came out with a ruling that said 'there really is nothing above an SPF of 15,' that [the FDA] was looking to the industry to follow that lead, but you still have classifications of a 30, 40 and 50. So the manufacturers come out and say 'yes, it's only a 15 in terms of what it can block, but it stays on two hours longer, therefore it gives you double the protection,"' he says. "It's very confusing to the consumer and in turn, we're giving the consumer a false sense of protection when they get in the sun." Institut Esthederm has never put SPF numbers on it products in the U.S. market, Dean notes. "We've had classifications that say either 'moderate,' 'high' or 'very high' protection depending on what the product was developed for."

Sothys' Arnaud is also very concerned about a false sense of security that consumers may have when they use sun care products. She explains that many people don't realize that when a product is waterproof, it does not mean that it's 'towelproof.' While a lotion or spray may stay on during a swim, as soon as consumers wipe their faces with a towel, the product is no longer effective and it needs to be reapplied.

So long as consumers are given the right information on how to protect themselves from the sun, however, the products that are on the market can be quite effective -- and future sun care products, according to Dean, will be even

more effective. -"I think that as we learn more about sun damage, there is going to be technology that allows us to adapt to the sun rather than stay out of it. I don't think it's realistic to think that in the future we're all going to be wearing space suits so that we have no sun exposure whatsoever. The technology is there, it's being developed, and it will be expanded upon so we teach the body how to protect itself more effectively rather than constantly fighting against it."

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HEADLINE: The US Cosmetics and Toiletries Sector in 1995: Part II

HIGHLIGHT: Market analysis of cosmetics & toiletries sector for 1995 is detailed by segment star performer is skincare

BODY:

The star performer in the past 5 yrs in the US cosmetics and toiletries sector has been the skincare market as the sector has been driven by heavy investment in new products and a huge growth in demand for products with visible effects. The US fragrance market grew at a CAGR [Compound Annual Growth Rate] of 2.9% in 1991-95 to a value of $5.899 bil. One trend in this area is the creation of male and female fragrances like cK one. The haircare market was worth $4.626 bil in 1995 and has been driven by the success of niche products once found only in hair salons but now widely available. The segment has also been one that has allowed the successful marketing of products aimed at specific ethnic groups. Sales of makeup rose only 1.2% in 1995 to $3.387 bil a major fight for market share in this segment is expected. The male toiletries market is a $1.7 bil proposition and the dominant marketer is Gillette with over 47% of razors by value and some 18% of shaving preparations. The toothpaste category is worth $1.6 bil, with the number one spot contested by Procter & Gamble and Colgate-Palmolive. The oral hygiene market is worth $2.9 bil overall. The personal hygiene sector was worth $4.321 bil in 1995. The overall skincare market was $3.567 bil in 1995, with a major driver being anti-aging products in addition to concerns about suncare. The article includes significant additional information, including projections on future trends. A graph indicating market size by sector for 1995-2000 has been omitted due to keying restrictions.

U.S. cosmetics and toiletries market analysis

The star performer in the last five years has been the skincare market. Growth in skincare sales has been driven by heavy investment in new products, and by a massive growth in demand for treatments that have clearly visible effects. Consumers want the 'dream in the bottle' to become real, and they have shown themselves willing to pay for it.

Fragrances: breaking down traditional divisions

The U.S. fragrance market grew steadily at a CAGR of 2.9 percent over the period 1991-1995, to a value of $5.899 billion. From 1993 to 1995 the market grew above consumer price inflation, and this expected to continue as the U.S. emerges from recession.

New marketing concepts have been developed and established classifications into male and female fragrances as well as mass and fine fragrances are becoming more and more blurred. While the prime example of this is obviously Calvin Klein's highly successful of cK one, other new fragrances have also exploited this trend.

In 1995, taxes changed in the U.S. for fragrances as a result of GATT. Federal excise duties on imported perfume containing alcohol were abolished and a tax rebate on distilled spirits used in the domestic production of perfume was introduced.

Haircare: specialist products for special requirements

The haircare market was worth $4.626 billion in 1995 and grew at just above the rate of the overall sector between 1991 and 1995. The haircare market has been driven by the success of niche products that were once found only in hair salons but are now widely available in drug stores, supermarkets and often mass merchandiser. New products such as leave-in conditioners and color shampoos have been driving market growth in value terms over the 1993-95 period. Shampoo dominates the haircare market, being by far the largest category ($1.791 billion in 1995).

In the past, many of the larger retailers traditionally merchandised the haircare categories separately ie., shampoo was merchandised separately from conditioner. Wal-Mart was one of the first retailers to go against this tendency, and moved the "salon inspired" and "professional" haircare products into a separate section. This means, for example, that Alberto Culver's VO5 brand of shampoo, conditioner and Hot Oil treatment would all be merchandised together.

Haircare has been one of the key markets for the growth of sales of products targeted at specific ethnic groups in 1990s. The pattern of this growth has offered considerable insight into how the structure of the whole cosmetics and toiletries sector is set to change in the next few years. What was once a niche market has been wholeheartedly adopted by mainstream U.S. retailers, and specially by the mass merchandisers. Companies such as Wal-Mart have seen growth far above the national average, in what has been an above-average growth category, anyway. While there is some evidence that sales of ethnic haircare products have slowed recently, the category nonetheless offers pointers to the development of similar niches in the future.

Makeup: the return of glamour?

Sales of makeup rose by only 1.2 percent in 1995, to $3.387 billion. The market has suffered from a decline in retail value to promotional campaigns by various retailers to gain market share. Some analysts have also suggested that the market has suffered from "clinicalizing" the industry, the same process that has benefited the skincare market, taking away the fun element of color cosmetics.

As already described, there will be a major fight for market share in color cosmetics over the next few years. Leading marketers have been strengthening their positions through raising extra funds or through the acquisition of smaller players. L'Oreal's purchase of Maybelline will make the company's U.S. division (Cosmair) the marketer to watch in the mass market in the next couple of years, while Estee Lauder's IPO, as well as its acquisition of MAC and Bobbi Brown, will strengthen its position as a formative influence in the premium sector.

Male Toiletries: developing the other half of the population

Growth in the $1.7 billion males toiletries market (defined here as wet razors and shaving preparations only) has been driven in the 1990s by increased sales upscale variants of the basic products. Thus, systems have grown at the expense of foam. The dominant marketer in male toiletries is, of course, Gillette, with more than 47 percent of razors by value, and nearby 18 percent of shaving preparations. Private label has had little impact on this dynamic market, even though it is one dominated by mass retail channels.

Oral Hygiene: adding value to the basic routine

The number one spot in the key $1.6 billion toothpaste category is hotly contested between Procter & Gamble and Colgate-Palmolive, with the later just ahead in 1995. Not only is this by far the largest category in the $2.9 billion oral hygiene market, but it is also the fastest growing, driven in particular by the bicarbonate of soda segment. While the Arm & Hammer brand was the first to make this segment the engine of growth it has been in recent years, the major players were quick to step in with their own versions, and the Colgate Baking Soda product now accounts for some five percent of the overall toothpaste category. Elsewhere in oral hygiene, growth has been far slower as mass merchandisers have carved themselves a greater slice of sales.

Personal Hygiene: the emergence of a retail-led category

The U.S. personal hygiene market was valued at $4.321 billion in 1995. Value has been growing ahead of volume, driven by two main factors. Firstly, more products are aimed at niche markets: marketers are expanding the market by segmenting the customer base further to target specialist groups with products such as "natural" soaps and non-talc body powder. Secondly, the bath and shower category has seen a great number of major value-added new product launches, such as Jergens Body Shampoo and Dove Cream.

Strong sales in the bath and body segment are heavily reliant on merchandising strategies. With the proliferation of new products in this category over the past few years, space management has become increasingly important. Some retailers have tried to stock a wide range of the new products that have been introduced, but the overall result has often been too many SKUs which ultimately just confuses the customer. Retailers such as Wal-Mart and K-Mart (among others) have repositioned the category away from conventional health and beauty aids aisles to an area closer to cosmetics.

Skincare: making the dream in a bottle become real?

The overall skincare market grew to $3.567 billion in 1995, representing the highest overall market growth in cosmetics and toiletries in the 1990s. The major driver of this market has been the marketing of anti-aging treatments and, related to this, the increased concern with sun protection products.

Skincare has become the prime area for targeting consumers' key priority of functionality in personal care. Sun protection factors are higher, moisturizers are expected to slow the aging process, and cleansers need to provide relief from the effects of population. What was once a cosmetic category has moved closer to healthcare, especially in the sun protection segment. All these extra expectations have caused prices to rise, but consumers appear to be willing to pay the extra if they feel the product justifies it by fulfilling specific healthcare and beauty requirements.

The future for U.S. cosmetics and toiletries markets

The next task for marketers in the U.S. cosmetics and toiletries sector is to push for renewed high growth in the sector in the final years of this century. Recent strong growth spurts have come from a general increase in incomes combined with a fashion for more conspicuous usage of cosmetics, or from other "fashions," including the more health-related ones such as "safe tanning." Part of these fashions has often been some well publicized scientific advance, such as AHAs, and much work in the big companies' research and development laboratories will be focused on finding the next AHA. Even without allowing for the appearance of this anticipated new boost to the skincare market, however, sales here are expected to growth fastest in the second half of the decade, as they have done in the following graph.

Price will be more important as traditional retail divisions are broken down

The main thrust of much of the new retail activity has been a focus on price. Larger retailers are consolidating significantly and private label is growing. The increase in private label penetration that has been observed in a number of the top grocery chains is far removed from traditional brand oriented strategies. These trends will increase retailer power and also impact cosmetics and toiletries, and this will depress the growth of the market in the value terms over the coming years.

With a possible decline in the younger generation's use of beauty products, the aging baby boomers will become an even more important market for the industry. Younger women have been found to place less importance on cosmetics and clothes than their older counterparts did at the same age. However, a growing proportion of the population will, in the future, be in the higher age groups. These sections of the population, especially the 40 to 59 age range, are more likely to spend money on anti-aging treatments, and this will make up some of the value lost to the price-led consumer.

The industry is set to consolidate further in the coming years

Early in 1996, two major acquisitions in the U.S. cosmetics and toiletries sector have increased the competitive pressure on leading domestic companies. L'Oreal's purchase of Maybelline and Unilever's of Helene Curtis strengthen the presence of the two European giants in the makeup and haircare markets, respectively. Among the leading

domestic players threatened by these acquisitions are Revlon and Procter & Gamble, and the rest of the 1990s are likely to see intensified competition in the world's largest market, with further concentration to come.

Two of the leading domestic marketers have announced plans to raise funds for this period by at least partially abandoning private status. Estee Lauder and Revlon have both made initial private offerings of a small proportion of their stock. While the current owners are not relinquishing a significant degree control, these public offering will nonetheless throw the companies open to a new level of public scrutiny.

The new funds raised by these leading domestic companies will help to maintain an edge in the all-important area of new product development and launching, although the major reason for Revlon's IPO is to relive the company of some of its long-term debt. If they are to compete with the emerging "mega-nationals," then companies such as Lauder and Revlon will have to invest heavily in their capacity to dominate sales in their chosen categories.

Jeremy Smith is a consultant specializing in worldwide cosmetics & toiletries markets as Datamonitor. Datamonitor is an independent strategic management consultancy which specializes in analyzing market and company dynamics. It has become a market leader in the provision of high quality off-the-shelf market reports and bespoke consultancy to business across the globe. For further information, contact Datamonitor Europe, (+44) 171 625 8548 or Datamonitor USA, (+1) 212 661 2525.

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HEADLINE: Tick Tock : The clock slows for no one. But, new ingredients, formulas, products, and technology claim to aid in the ultimate aging of skin; Brief Article

BYLINE: Sanabria, Virna

BODY:

One of the best compliments a person can receive is, "You have good skin." That comment is usually followed by, "What do you use?" Marketers hope the response has something to do with their products, which has something to do with the ingredients, formulas, surfactants, polymers, and so on. Global Cosmetic Industry got the "skinny" on some of the latest treatment cosmetic ingredients and products that claim "anti-aging," "moisturizing," "hydrating," and "sun protection" benefits.

According to Information Resources, Inc., Chicago, IL, anti-aging, bleaching, or fading skin-care products reached $ 343.6 million in sales, week ending May 21, 2000, an increase of 36.8 percent over last year. There is a significant demand for products offering these types of benefits, as well as a growing consumer trend for the kind of benefits offered. The most important trends in the topical skin-care solution market are:

* Anti-wrinkle products with a thin consistency

* Multifunctional products

* Solutions that include herbal/botanical extracts

* Self/naturally preserved or preservative-free products

* Skin fading and bleaching products

* Products offering anti-stress relieving qualities

* Protection against the environment (sun, wind, pollution, free radicals)

Sunsational

Thanks to a wealth of information available from doctors, advertising, media, and word-of-mouth, the average consumer is well-aware of the inevitable damage the sun will cause, and the importance of using **sunscreen.** Sun-care products, including suntan oils, lotions, and **sunscreens,** reached $ 499.9 million in **sales,** week ending May 21, 2000, an **increase** of 10.4 percent over last year. "**There** is a major thrust for **skin-care** products to include **sunscreens,**" says Marianne O'Donoghue, MD, Associate Professor of Dermatology, Presbyterian St. Luke's Medical Center, Chicago, IL. The market calls for **sunscreens** that block the broad-spectrum radiation of **UVA** and UVB rays. O'Donoghue offers, "effective ingredients are Avobenzone to block **UVA** rays, and Oxtocryline to block UVB rays."

A well-informed consumer "wants higher performance and **protection** in the products they buy specifically for the purpose of sun **protection,**" says Craig Bonda, manager/product development, Personal Care Additives, of HallStar, a division of C.P. Hall Company, Chicago, IL. HallStar recently introduced its newest ingredient, Hall Brite TQ (Diethylhexyl 2,6--naphthalate) or DEHN. "The best way to achieve full-spectrum **protection** is to incorporate Avobenzone into a formulation to attenuate UVA, and to photostabilize the Avobenzone with DEHN," Bonda explains. "DEHN was developed as a photostabilizer to help **prevent** sunscreen active ingredients from losing their absorbance in the sun. As a result, DEHN improves the overall performance of the sunscreen." DEHN can be formulated into the oil phase of sunscreen and other topically applied consumer products. DEHN serves more than one purpose: In formulations, it is a good solvent and emollient; it is cost-effective, replacing ingredients that may cost much more; and it is covered by a patent, meaning customers can practice technology. New technology such as DEHN is showing promise towards a sunscreen product that will ultimatley provide "total-spectrum" protection against UVA and UVB radiation.

Not Aging Gracefully

The largest population, the baby boomers, refuses to get old gracefully, and maintaining a youthful appearance is increasingly important to Gen X. The first order of defense against age is topical solutions. O'Donoghue suggests, "the most effective and liked prescription ingredient is tretinoid. Over-the-counter products that contain retinol are 10 percent less-effective, but work well. An important characteristic that facial topical solutions must have is a thin consistency."

Seppic Inc., a Fairfield, NJ-based chemical specialties company produces an ingredient claiming to reverse the signs of aging. "SEPILIFT[R]DPHP is the weapon against aging for the next millennium," says Marie-eve Koziol, cosmetics division director. SEPILIFT[R]DPHP is a lipoaminoacid obtained by grafting a fatty acid (palmitic acid) onto a amino acid (hydroxproline, an essential amino acid that is a building block of collagen) to create a plant-derived biological vehicle. "This process produces long-lasting moisturization and firming action. SEPILIFT[R] DPHP re-sculpts the face's skin, corrects imperfections, and delays the appearance of wrinkles by protecting the fibers of the dermis," claims Koziol. Because of its plant-derived ingredients, SEPILIFT[R] anti-aging action is holistic.

Results You Can Sea

Osea Products, Malibu, CA, combines natural ingredients from the ocean with innovative technology. The company's most recent launch, Eyes and Lips, is 100 percent natural, preservative-free, and offers anti-oxidant benefits of vitamins A, D, and E, with the active ingredient DPHP. Osea boasts it is the first company to incorporate the technology of DPHP in an eye and lip treatment. With vegetable-derived amino acid, DPHP is said to stimulate collagen fibers, moisturize, and reduce the appearance of wrinkles around the lips and eyes. Osea claims that after one month of using this product, the depth of wrinkles are significantly reduced by up to 60 percent, and the skin's moisture content is increased by 20 percent. Another important quality is the ultra-light consistency of a non-greasy cream solution. Osea products are currently available online at Sephora.com, or by calling 888-FOR-OSEA.

Grape Expectations

Marketers aim to answer the consumer's need for products that contain natural ingredients, as well as functioning hydration. "It's no secret that the French have always had a way with grapes," offers Lancome, producers of Vinefit SPF 15 Complete Energizing Moisturizer. "The most beneficial natural extract in the market today is grape seed, due to its anti-aging qualities," cites Debra Janliman, MD, clinical instructor at Mt. Sinai School of Medicine, and practicing dermatologist in New York. Vinefit is a daily moisturizer containing a formula that includes polyphenols, which offers broad functioning anti-oxidants along with vitamin B3 and SPF 15 **sunscreen protection.** The most important ingredient in the formula is grape, which provides skin with potassium, phosphorus, magnesium, and calcium to increase hydration in the skin. "Our extensive consumer research indicates women today want multifunctional products that are based on natural ingredients. We are meeting this consumer demand with Vinefit and believe this product will raise the bar for quality **skin-care** products in the prestige marketplace," says Michelle Taylor, senior vice president/marketing for Lancome. Vinefit will be available at Lancome counters in September.

Young Lips

Avon offers vitamins and retinol in its patent-pending formula that claims to reduce the signs of aging on lips. Anew Retinol Treatment reduces fine lines on lips by 40 percent. As with all other Avon products, Anew will be available through Avon representatives in July, 1-800-FOR-AVON, online at www.avon.com, and at more than 50 Avon Beauty Centers nationwide.

Beautiful Neck

Jurlique Skin Care, an Australia-based company, creates an intensive treatment for the neck. Because "the hands and neck are the first to show signs of aging," Jurlique introduces an organic formula said to reduce and prevent the signs of aging. A blend of herbs, vitamins, minerals, proteins, lipids, and oils in the Jurlique serum is said to improve and maintain a firm neck. The essential oils in the formula are: Myrrh oil, an antiseptic, anti-inflammatory oil good for dry skin; Neroli Oil, stimulates the growth of new cells; Orange oil, regenerates and soothes irritated acne-prone skin conditions; and Frankincense Oil, a tonic effect that helps restore tone and slows down the appearance of wrinkles. Jasmine is added to the array of natural ingredients for its aromatherapy benefits.

Mass Miracles

Truth be told, many treatment cosmetics usually come with high-price tags. Mass-marketers like St. Ives offer these types of skin-care products, without the high cost. St. Ives offers a smooth-even pallet with its new St. Ives Dark Spot Fade Cream. The new skin-fading cream contains a patented formula with natural Swiss botanicals, vitamins A (retinol), C, E, and hydroquinone. The cream effectively lightens dark spots and skin discoloration. St. Ives claims to reduce age spots by an average of 44 percent, in just eight weeks. Each ingredient in the new product plays an active role: the active ingredient hydroquinone lightens hyper-pigmented areas of the skin by suppressing the formation of melanin in the skin cells; vitamin A (retinol) exfoliates dead cells from the skin's surface; vitamin C helps even out skin-tone; and vitamin E provides anti-oxidant protection for the skin. Using a patented Microsponge[R] technology, the benefits of the ingredients are delivered to the skin in a timely manner. St. Ives Dark Spot Fade Cream will be available at mass-market retailers nationwide in August .

Millennium Miracles

Due to the harmful effects (and growing awareness) of UV-rays--not to mention many consumer concerns for premature aging--effective, multifunctional products that carry claims of "reduction," "protection," and "anti" capture customer attention. The skin-care industry is moving with the fast pace of technology. As the consumer demands naturally derived skin-care products, marketers answer with products that combine botanicals benefits and innovative technology. Plus, the products claim to produce results. And, results are exactly what the consumer wants to see.

Virna Sanabria is GCI's associate editor. To comment on this or any GCI story, contact her at (212) 951-6719.

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Southern California Living; View Desk

Do I Look Older? Baby boomers are getting, um, more mature. The generation is now chasing the fountain of youth with 'cosmeceuticals.'

BARBARA THOMAS
TIMES STAFF WRITER

It might start with a line across the forehead that deepens into a wrinkle, or skin that suddenly appears dull looking. Whatever the signal, aging skin tends to hit women square in the face in their mid- to late 40s.

"Forty-six was a disaster," recalled actress Linda Evans, now 56. "You look into the mirror one day and you see your mother."

Other baby boomers may be experiencing such a rude awakening, but they also may be a lucky bunch. They are the first generation to have access to products that simply did not exist in their mothers' time or were available only in doctors' offices as recently as 10 years ago.

Pond's Clean Solutions Combination Skin Moisturizer, Oil of Olay Daily Renewal Cream and some products sold in spas contain glycolic and beta-hydroxy acids that exfoliate and smooth the skin. Estee Lauder Diminish is one of many creams that contain Retinol, which reduces the appearance of fine lines.

Welcome to the world of "cosmeceuticals"--beauty aids that are hybrids of cosmetics and pharmaceuticals. These over-the-counter products contain ingredients approved by the Food and Drug Administration for sale without prescriptions. They are supposed to help protect the skin against the ravages of aging, sun exposure and smoking, and consumers in the millions are buying these products at department and drugstores.

"We're at a time where things really work," said Santa Monica dermatologist Karyn Grossman, who shares her office with a plastic and reconstructive surgeon,

1/21/00 LATIMES E1
(Publication page references are not available for this document.)

Today, many cosmetics companies, including Pond's, Avon and Elizabeth Arden, are doing a lot of research in skin repair.

"I'm not saying that all companies are good. They are not. But some of them have made extraordinary contributions," said Amy E. Newburger, a Scarsdale, N.Y., dermatologist who has just written "Looking Good at Any Age," (Doubleday).

Cosmeceuticals may help for a time, but at some point the natural process of aging may not be held at bay with topical applications of cosmeceuticals.

Some significant skin changes, for example, are unavoidable because of genetically triggered biological changes within a person, Newburger explained.

Women, for example, undergo great hormonal changes during menopause, which begins usually in their mid- to late 40s and affects the skin. The results can be acne, increased rosacea, even increased blood-vessel dilations on the face.

Another big change is the decline in skin-cell growth, which results in dull-looking skin. The normal skin-cell renewal rate for a young person is four weeks.

But with all the interest in cosmeceuticals there are some caveats. These products are considered cosmetics, which are loosely regulated. The FDA, however, is concerned about liberal advertising claims, said Bill Martineau, a health care analyst for Freedonia.

While prescription drugs must go through a series of clinical tests before they can be approved by the FDA, cosmetics companies have to show only that they use safe ingredients, not that they specifically result in demonstrable changes in the skin.

At lot of these claims may not be printed, but even consumers as savvy as dermatologist Grossman hears outrageous claims. That means consumers are pretty much left on their own to assess highly subjective results.

"I think the only problem is that the consumer may be deluded into thinking that they're getting more of a benefit than they are," said Joshua Wieder, assistant clinical professor of dermatology at UCLA.

And for some like actress Evans, the solution to her rude awakening 10 years ago--before cosmeceuticals--was plastic surgery, a decision she regrets: "I looked better afterward, but I wish I had had another choice."

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(Publication page references are not available for this document.)

Now she tries to prevent further aging with cosmeceuticals. She even has her own line--Rejuvinique, an at-home skin-care treatment that uses antioxidant creams to protect and a mask with electrical impulses to stimulate the skin.

Much of her aging could have been avoided if she had simply used sunscreen. Today, she lives happily in rainy Seattle.

Barbara Thomas can be reached at barbara.thomas@latimes.com.

TABULAR OR GRAPHIC MATERIAL SET FORTH IN THIS DOCUMENT IS NOT DISPLAYABLE

GRAPHIC-DRAWING: (no caption), VAL B. MINA / For The Times;

---- INDEX REFERENCES ----

COMPANY (TICKER): Johnson & Johnson (JNJ)

KEY WORDS: BEAUTY INDUSTRY; COSMETICS; AGING

NEWS SUBJECT: Los Angeles Times; Newspapers' Section Fronts; World Equity Index (LATM FRT WEI)

NEWS CATEGORY: TOP STORY; MAIN STORY

INDUSTRY: Drug Manufacturers; Advanced Technology Medical Devices; Medical & Biological Technology (DRG MDV MTC)

EDITION: HOME EDITION

Word Count: 983
1/21/00 LATIMES E1
END OF DOCUMENT

National Library of Medicine: IGM Full Record Screen

Related Articles | External Links

TITLE:	**Solar keratoses and their relationship to non-melanoma skin cancers.**
AUTHORS:	**Kocsard E**
AUTHOR AFFILIATION:	**St Vincent's Hospital, Darlinghurst, New South Wales, Australia.**
SOURCE:	**Australas J Dermatol 1997 Jun;38 Suppl 1:S30**
CITATION IDS:	**PMID: 10994468 UI: 20449964**
ABSTRACT:	**Solar keratoses belong to the list of clinically invisible dermatoses, as the loss of their horny layer may create the illusion that they have disappeared, and numerous subclinical lesions can be highlighted by 5-fluorouracil therapy. Solar keratoses are recognized as potential precursors for squamous cell carcinoma. However, basal cell carcinoma (BCC) may develop in a soft type of solar keratoses as a consequence of migration of pluripotential adnexal epithelial cells in reparative response to trauma, particularly in areas rich in adnexal structures, such as the face. These intraepithelial resident adnexal cells may result in the development of BCC following chronic solar exposure and damage.**
MAIN MESH HEADINGS:	**Carcinoma, Basal Cell/*pathology Carcinoma, Squamous Cell/*pathology Keratosis/*pathology Precancerous Conditions/*pathology Skin Neoplasms/*pathology Sunlight/*adverse effects**
ADDITIONAL MESH HEADINGS:	**Australia/epidemiology Carcinoma, Basal Cell/epidemiology Carcinoma, Squamous Cell/epidemiology Environmental Exposure/adverse effects Female Human Incidence Keratosis/epidemiology Male Precancerous Conditions/epidemiology Risk Assessment Skin Neoplasms/epidemiology 2000/10 2000/07 11:01**
PUBLICATION TYPES:	**JOURNAL ARTICLE**

REVIEW
REVIEW, TUTORIAL

LANGUAGES: **Eng**

National Library of Medicine: IGM Full Record Screen

Related Articles | External Links

TITLE: Incidence rates of skin cancer in Townsville, Australia.

AUTHORS: Buettner PG; Raasch BA

AUTHOR AFFILIATION: School of Public Health and Tropical Medicine, James Cook University, Townsville, Australia. petra.buttner@jcu.edu.au

SOURCE: Int J Cancer 1998 Nov 23;78(5):587-93

CITATION IDS: PMID: 9808527 UI: 99023713

ABSTRACT: Worldwide, incidence rates of skin cancer are increasing alarmingly in populations of predominantly Caucasian origin. A prospective population-based survey, set up to collect epidemiological information on all excised and histologically confirmed skin cancers, started in Townsville, Australia (population of 127,000) in December 1996. Data on the anatomical distribution of skin cancer has been collected using a detailed body map. Estimations of type-specific and site-specific incidence rates were age-standardized according to world standard population. Site-specific incidence rates were adjusted for surface proportion of the body site and are given per 100,000 body units. Between December 1996 and December 1997, a total of 3,536 patients with 5,945 histologically confirmed skin cancer lesions were recorded. Age-standardized incidence rates of basal cell carcinoma were 2,058.3 for men and 1,194.5 for women, 1,332.3 for men and 754.8 for women for squamous cell carcinoma, and 49.1 for men and 41.7 for women for cutaneous melanoma (CM). Site-specific incidence rates of non-melanocytic skin cancer were extreme on sun-exposed areas of the face, whereas site-specific incidence rates of CM were highest for neck, posterior trunk and face. Less exposed body sites, such as unexposed upper limbs or thighs, showed reduced incidence rates for all types of skin cancer. Tropical North Queensland has the world's highest incidence rates of skin cancer of all types. Site-specific incidence rates demonstrate that highly sun-exposed body sites are at high risk of developing skin cancer and provide, therefore, strong indirect evidence for the causal relationship between sun exposure and skin cancer.

MAIN MESH HEADINGS: Skin Neoplasms/*epidemiology

ADDITIONAL MESH HEADINGS:
Adult
Aged
Australia/epidemiology
Carcinoma, Basal Cell/epidemiology
Carcinoma, Squamous Cell/epidemiology

Female
Human
Incidence
Male
Melanoma/epidemiology
Middle Age
Support, Non-U.S. Gov't
2000/06
2000/20 09:00

PUBLICATION TYPES: JOURNAL ARTICLE

LANGUAGES: Eng

Related Articles | External Links

TITLE:	Body site distribution of cutaneous malignant melanoma in relationship to patterns of sun exposure.
AUTHORS:	Elwood JM; Gallagher RP
AUTHOR AFFILIATION:	Department of Preventive and Social Medicine, University of Otago, Dunedin, New Zealand.
SOURCE:	Int J Cancer 1998 Oct 29;78(3):276-80
CITATION IDS:	PMID: 9766557 UI: 98437947
ABSTRACT:	A study of all newly incident melanoma patients in British Columbia in 1991-1992 was undertaken to test the hypothesis raised by an earlier study, which showed that in younger patients the incidence rate of melanoma per unit area of skin was higher on intermittently exposed skin areas than on continuously exposed areas. Using 1,033 patients and a more detailed body site categorisation than was previously possible, our results confirmed that in both men and women under age 50 the highest melanoma density was on the back. At ages over 50, the greatest density occurred on fully exposed sites, such as the face, though the dorsum of the hand and forearm, likely also to have high exposure, show very low melanoma densities. Differences between males and females correlate well with differences in likely exposure patterns. These results were seen for all invasive cutaneous melanomas combined; the patterns were similar for subtypes and for both invasive and in situ melanoma, with the exception of lentigo maligna melanoma (LMM), which occurs almost exclusively on the face, even at younger ages. Comparison with the earlier study (1976-1979) shows that the age-standardised rates for melanoma excluding LMM have increased by 60%, with the greatest proportional increase being at younger ages; in the recent data, the age-standardised rate for intermittently exposed sites exceeds that for usually exposed sites. Our results confirm that intermittent sun exposure has a greater potential for producing melanoma than continuous exposure at ages below about 50, though at older ages melanoma is more common on body sites with continuous sun exposure.
MAIN MESH HEADINGS:	Melanoma/*epidemiology Skin Neoplasms/*epidemiology Sunlight/*adverse effects
ADDITIONAL MESH HEADINGS:	Adolescence Adult

Age Factors
British Columbia/epidemiology
Carcinoma in Situ/epidemiology
Carcinoma in Situ/pathology
Female
Human
Incidence
Male
Melanoma/pathology
Middle Age
Neoplasm Invasiveness
Organ Specificity
Registries
Sex Factors
Skin Neoplasms/pathology
Support, Non-U.S. Gov't
2000/06
2000/20 09:00

PUBLICATION TYPES: **JOURNAL ARTICLE**

LANGUAGES: **Eng**

National Library of Medicine: IGM Full Record Screen

Related Articles | External Links

TITLE:	**Histopathologic variants of basal cell carcinoma correlation with sex, age and localization.**
AUTHORS:	**Puizina-Ivic N; Matokovic B; Gluncic I; Maslovara S; Vela-Ljubic J**
AUTHOR AFFILIATION:	**Clinical Center Split, Department of Dermatovenereology, Hrvatska-Croatia, Europe.**
SOURCE:	**J Med Syst 1999 Oct;23(5):389-400**
CITATION IDS:	**PMID: 10587919 UI: 20055231**
ABSTRACT:	**During the 6-year period (January 1, 1993 to December 31, 1998) in the Laboratory for Dermatopathology of Department of Dermatovenereology in Clinical Hospital Split, 1616 basal cell carcinomas (BCC) of a total of 323 investigated specimens were diagnosed. The incident rate varies from 92 to 114 BCC per 100,000 inhabitants in the Split region. The sex ratio in material is 1.2:1 in favor of males. The frequence of BCC increases with the advanced age in both sexes with the peak in the age group from 70 to 79 years. The most frequent location in both sexes is the nose followed by cheeks and trunk. Statistic analysis showed a significantly higher occurrence of BCC in temporal region in the males and perioral region in the females; respectively. The solid variant is the most frequent followed by superficial multicentric and solid-adenoid. Pure variants are found in 83.1% specimens, and mixed variants in 16.9%. Solid and adenoid variants are the most frequent on the nose and cheeks. According to statistics cystic variant is significantly higher on the forehead, and morpheic variant on the nose. Superficial multicentric variant is statistically more frequent on the trunk than on other locations. All specimens were reexamined and histopathologic variants were obtained. Over 2000 data are comprised which is a sufficient examination sample. In programs such as SPSS, and Graph master ver 1.12, Win95, MO'97 (Word, Excel, Access) on Pentium II 200 MHz, floppy, 64 MB RAM, HDD 2.1 GB, CD x24, HP LJet 6L, a comprehensive analysis has been performed.**
MAIN MESH HEADINGS:	**Carcinoma, Basal Cell/*epidemiology** **Skin Neoplasms/*epidemiology**
ADDITIONAL MESH HEADINGS:	**Adult** **Age Distribution** **Aged** **Carcinoma, Basal Cell/pathology**

Croatia/epidemiology
Female
Human
Incidence
Male
Middle Age
Sex Distribution
Skin Neoplasms/pathology

PUBLICATION TYPES: **JOURNAL ARTICLE**

LANGUAGES: **Eng**

Geographic Pathology of Skin Cancer

Urbach F. Geographic Pathology of Skin Cancer. In: Urbach F, ed. Biologic effects of ultraviolet radiation (with emphasis on skin). Oxford Pergamon Press, 1969:635–653.

Robert Jackson

Abstract

Background: The development of knowledge concerning the role of sun exposure in causing skin cancer has been a gradual one.

Objective: This article reviews the article by Urbach who used manikin coated with an ultraviolet dosimeter to see exactly where on the head and neck the exposure was greatest.

Conclusion: Urbach showed that the areas of greatest sun exposure on his manikins corresponded with the location of 95% of squamous cell carcinoma and 66% of basal cell carcinoma. He also clearly showed the importance of scattered sky and reflected radiation.

Sommaire

Antécédents: La connaissance du role de l'exposition au soleil dans le cancer de la peau s'est élargie progressivement.

Objectif: Étudier l'article d'Urbach, qui s'est servi de mannequins et d'un dosimètre pour trouver quelles zones de la tete et du cou étaient le plus exposées au rayonnement UV.

Conclusion: Urbach a montré que les zones les plus exposées sur les mannequins correspondaient aux régions touchées par 95% des carcinomes spinocellulaires et par 66% des carcinomes basocellulaires. Il a également démontré l'incidence des nuages dispersés et des rayons réfléchis dans le cancer.

By way of an introduction, let me point out a few of the important background studies delineating the relationship between habitual exposure to sun and the development of skin cancer.

We should recall the "Seemanshaut" (sailor's skin) as described by Paul Gerson Unna, from Hamburg, in the 1890s. In the sun-exposed skin of light-complexioned German sailors, Unna described the clinical effects of habitual sun exposure, which he found were not uncommonly associated with skin cancers.[1]

It is also helpful to remember J.H. Hyde's exceptional article in 1906.[2] The article was entitled "On the influence of light in the production of cancer of the skin." Using three cases of xeroderma pigmentosum, Hyde proceeded to use this disease as nature's example of accelerated damage due to ultraviolet light. He also tried, using very crude cancer death statistics from the United States, to show that deaths from head, face, and neck cancer, presumably mostly cancer of the skin, were much lower in those states which had a high percentage of Afro-Americans in their population.

Another milestone was Findlay's report[3] in 1928 that showed that mice exposed to ultraviolet light for 8 months developed "papillomata and malignant epitheliomata of the skin."

The final signpost I wish to mention is that of Blum's work on the carcinogenic rays of ultraviolet light, interpreted by him along with the experimental, statistical, and epidemiological evidence, and summarized in his 1948 paper[4] entitled "Sunlight as a causal factor in cancer of the skin in man."

Frederick Urbach was born in Austria in 1922. He graduated in medicine from Jefferson Medical College in Philadelphia in 1946. After a stint as head of cancer research at the Roswell Park Memorial Institute in Buffalo from 1955 to 1958, he moved to the Skin and Cancer Hospital at Temple University in Philadelphia, where he became Medical Director and Chief of Dermatology for many years. Dr. Urbach was an outstanding authority on the biological effects of ultraviolet radiation and on cutaneous cancer. He wrote over 100 papers and at least two books.

Urbach would have known of the articles reviewed in the introduction. The ultraviolet light dosimeter had been known for some time. What stimulated him to use the dosimeters on the manikin is not known. I can remember well his presenting slides of his varying coloured manikins at a plenary session of the American Academy of Dermatology meeting. It was clearly the work of a clever mind.

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Emeritus Professor, Medicine, University of Ottawa, Ottawa, Ontario, Canada.

Address for correspondence: Dr. Robert Jackson, 1081 Carling Avenue, Suite 508, Ottawa, ON Canada K1Y 4G2

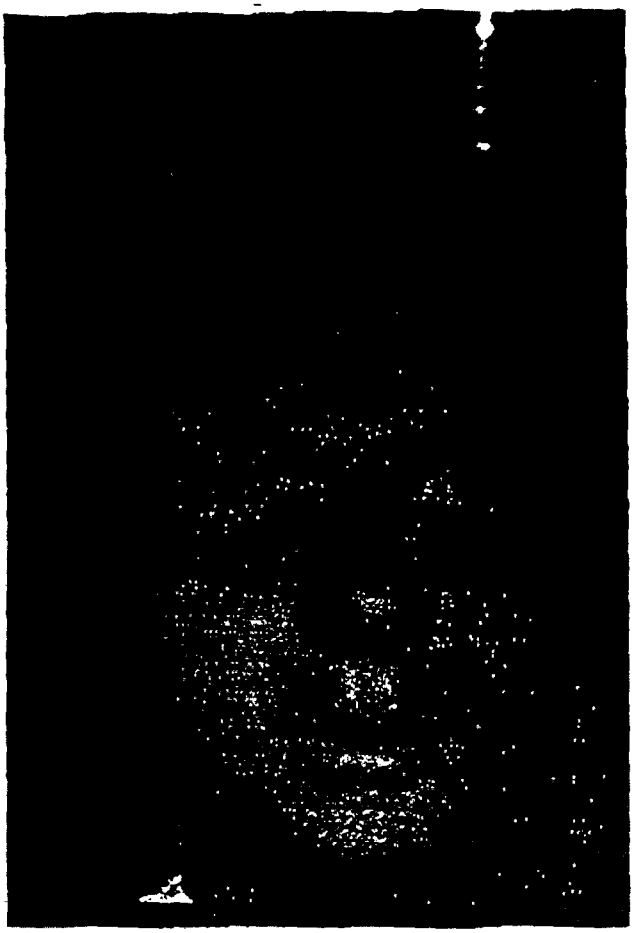

Figure 1 Distribution of "normal" ultraviolet light with sun angle at 65° and ground reflection of 3%. Lighter coloured areas, such as the orbit and on the central portion of the upper lip, indicate less sun exposure [from Urbach F. Geographic pathology of skin cancer. In: Biologic effects of ultraviolet radiation (with emphasis on skin). Oxford Pergamon Press 1969:643].

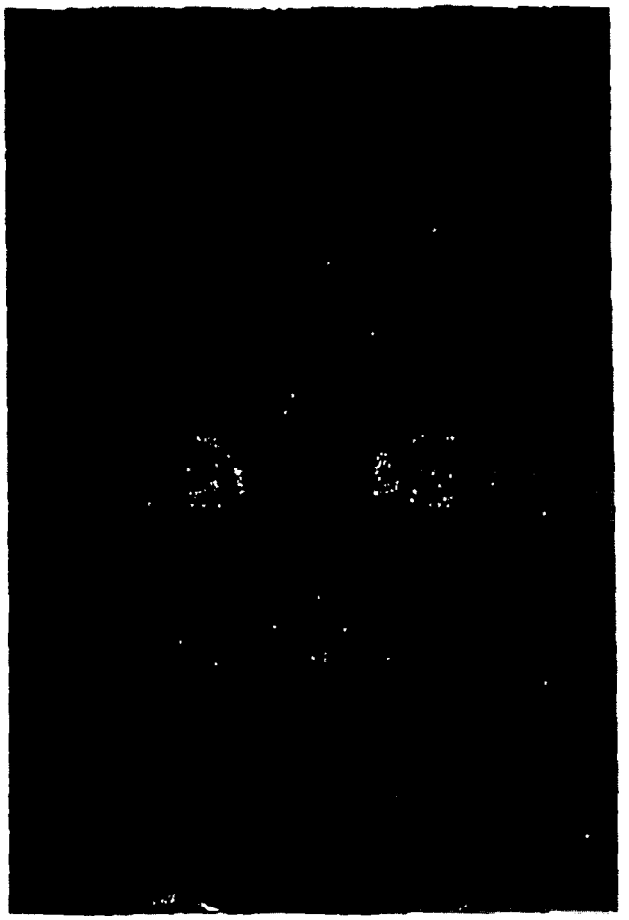

Figure 2 Distribution of ultraviolet light exposure seen from a highly reflective sand giving a ground reflection reading of 65% [from Urbach F. Geographic pathology of skin cancer. In: Biologic effects of ultraviolet radiation (with emphasis on skin). Oxford Pergamon Press 1969:643].

Urbach's Paper

In order to measure the actual amount of ultraviolet light that strikes the irregular surface of the head and neck, Urbach coated manikin with a chemical ultraviolet dosimeter.* On the roof of the Skin and Cancer Hospital in Philadelphia, he exposed them to sunshine under a variety of circumstances (Figs. 1–3).

Urbach said that there were three ways that ultraviolet light could reach the head and neck. Direct sun radiation accounted for 50%. The other 50% came mainly from multidirectional scattered sky radiation. This explained why it was possible to receive a sunburn even though one was sitting beneath a parasol. The remainder of the second 50% came from reflected radiation, from such items as sand on a beach and the aluminum on the bottom of a boat, and was quite variable in amount.

Reflected radiation was also found to be significantly increased to the neck from a white shirt collar. Light tan-painted plywood, grass, rimless eyeglasses, and water were not shown to cause increased reflected radiation. (The fact that water is a good reflector of sunlight is confirmed because so many of the microorganisms near the surface of the ocean use ultraviolet light as their source of energy, and after a certain depth these organisms can no longer survive.) Urbach presumed that beach sunburns are due to several factors. He mentioned reflection from the sand, a clearer atmosphere, and more sky radiation because of lack of obstruction by mountains, trees, and houses.

Urbach demonstrated that the orbital area, the upper lip beneath the nose, the vermilion of the upper lip, the anterior neck under the chin, and the retroauricular and

*The ultraviolet light dosimeter was a mixture of hexachlorocyclopentadiene, methyl yellow, and stearyl alcohol in a wax vehicle that has been layered on by dipping the manikin into a heated vat of the mixture.

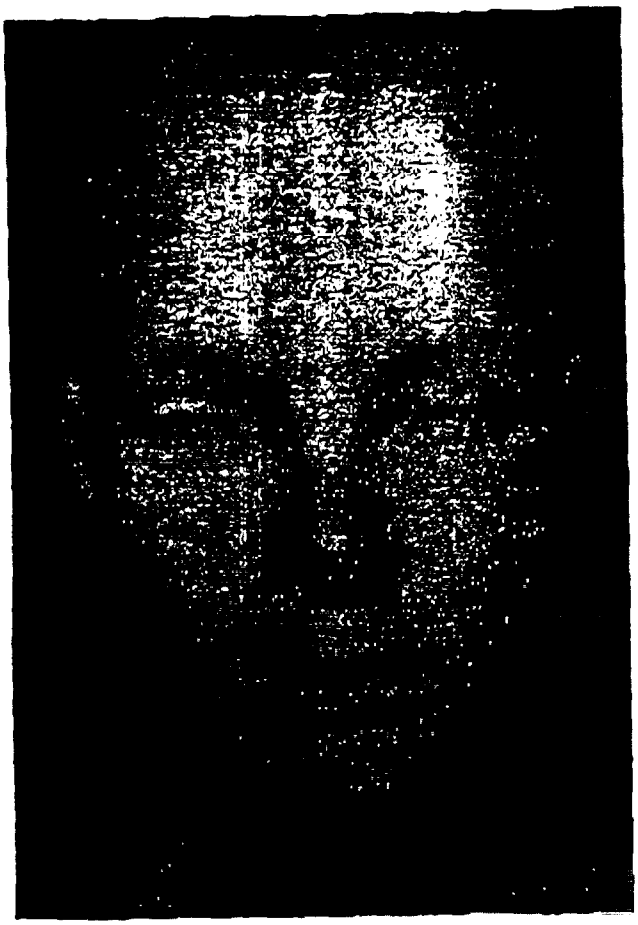

Figure 3 Distribution of ultraviolet light exposure under a parasol, with a horizon shade to exclude sky radiation and a shade to exclude ground reflection (from Urbach F. Geographic pathology of skin cancer. In: Biologic effects of ultraviolet radiation (with emphasis on skin). Oxford Pergamon Press 1969:643].

nasolabial fold areas were relatively protected. The areas receiving the most radiation were the tops of the ears, the nose, the scalp, and the posterior lower neck.

Urbach then took this information that he had learned from his manikins and applied it to reports of localizations of basal cell and squamous cell cancers on the head and neck. He found that there was a 95% correlation between the prevalence of squamous cell cancer and areas of high exposure to ultraviolet light. By contrast, he found only a 66% correlation between ultraviolet light exposure and the location of basal cell cancers. He pointed out that this meant that there were other significant factors in the development of basal cell cancers.

The next step in Urbach's paper was the creation of a world-sunburn map, corrected for latitude, cloud-cover and altitude (Fig. 4). Then he attempted briefly to correlate skin colour, ethnic origin, and prevalence.

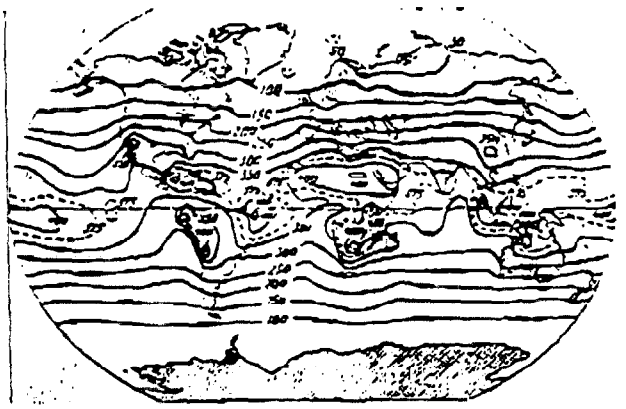

Figure 4 World sunburn map [from Urbach F. Geographic pathology of skin cancer. In: Biologic effects of ultraviolet radiation (with emphasis on skin). Oxford Pergamon Press 1969:647].

Comment

Twenty years after his 1969 paper, Urbach reviewed the possible role of the decrease in the ozone layer as a cause of the rapid increase in nonmelanoma skin cancer during the period from 1969 to 1989.[5] He showed quite convincingly that there was not nearly a large enough decrease in the ozone layer to explain the increase during that period of time. Among the factors that he listed as important were more leisure time, more money to go to sunny climes, more (better) health to allow outside activities including travel, and the obvious fact that people now wear less clothes. These four reasons are not sufficiently emphasized when addressing methods of control of the increased and increasing prevalence of nonmelanoma skin cancer.[6]

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2. Hyde JN. On the influence of light in the production of cancer of the skin. Am J Med Sci 1906; 131:1–22.
3. Findlay GM. Ultraviolet light and skin cancer. Lancet 1928; ii:1070–1073.
4. Blum HF. Sunlight as a causal factor in cancer of the skin of man. J Natl Cancer Inst 1948; 9:247–253.
5. Urbach F. Potential effects of altered solar ultraviolet radiation on human skin cancer. Photochem Photobiol 1989; 50:507–513.
6. Robinson JK, Rigel DS, Amonette RA. Trends in sun exposure knowledge, attitudes, and behaviors: 1986 to 1996. J Am Acad Dermatol 1997; 37:179–186.

National Library of Medicine: IGM Full Record Screen

Related Articles | External Links

TITLE:	Basal cell skin carcinoma and other nonmelanoma skin cancers in Finland from 1956 through 1995 [see comments]
AUTHORS:	Hannuksela-Svahn A; Pukkala E; Karvonen J
AUTHOR AFFILIATION:	Department of Dermatology, University of Oulu, Finland.
SOURCE:	Arch Dermatol 1999 Jul;135(7):781-6
CITATION IDS:	PMID: 10411152 UI: 99336933
COMMENT:	Comment in: Arch Dermatol 1999 Jul;135(7):843-4
ABSTRACT:	OBJECTIVE: To study trends of nonmelanoma skin cancer in Finland. DESIGN: Descriptive analysis of incidence and mortality rates for basal cell skin carcinoma (BCC) and other non-melanoma skin cancers (NMSCs) from 1966 and 1956, respectively, through 1995 in relation to sex, age, anatomical distribution, place of residence, and occupation. SETTING: Data were obtained from the nationwide Finnish Cancer Registry, to which reporting of skin cancer is compulsory. PATIENTS: Inhabitants of Finland (5.1 million in 1998). MAIN OUTCOME MEASURES: Age- and sex-specific incidence and mortality rates and overall rates adjusted for age to the world standard population; occupation-specific standardized incidence ratios, with the total Finnish population as reference. RESULTS: The age-adjusted incidence rate in 1991 through 1995 for BCC was 49 per 100,000 person-years in men and 45 in women. For NMSC it was 8.7 in men and 5.3 in women. Both cancer types showed an increasing trend in incidence rates. The proportion of tumors in the face, scalp, and neck was 59% for BCC and 67% for NMSC. The incidence rate of NMSC increased from north to south, while there was no great urban-rural or occupational variation in the occurrence of NMSC. The incidence rate for BCC was higher in urban than in rural regions. Farmers, forestry workers, and fishermen showed low incidence of BCC, whereas occupations with a high level of education or compulsory health checkups and medical care occupations appeared to have an increased incidence of BCC. The mortality rate for BCC in 1991 through 1995 was 0.08 per 100,000 person-years in men and 0.05 in women, and for NMSC, it was 0.38 in men and 0.23 in women. The mortality trend was decreasing for both cancer types. CONCLUSIONS: The incidence of NMSC is fairly low in Finland, accounting for 3.5% of all new cancer cases. Conversely, BCC is the most common cancer type. The incidence trend is increasing for both skin

	cancer types, but mortality remains low.
MAIN MESH HEADINGS:	**Carcinoma, Basal Cell/*epidemiology** **Skin Neoplasms/*epidemiology**
ADDITIONAL MESH HEADINGS:	**Aged** **Female** **Finland/epidemiology** **Human** **Incidence** **Male** **Occupational Diseases/epidemiology** **Support, Non-U.S. Gov't** **1999/07** **1999/20 10:00**
PUBLICATION TYPES:	**JOURNAL ARTICLE**
LANGUAGES:	**Eng**

National Library of Medicine: IGM Full Record Screen

Related Articles | External Links

TITLE:	Common skin cancers in the United States: a practical guide for diagnosis and treatment.
AUTHORS:	Leber K; Perron VD; Sinni-McKeehen B
AUTHOR AFFILIATION:	Department of Dermatology and Cutaneous Surgery, University of South Florida, Tampa 33612, USA.
SOURCE:	Nurse Pract Forum 1999 Jun;10(2):106-12
CITATION IDS:	PMID: 10542587 UI: 20010300
ABSTRACT:	Cutaneous malignancies are the most common cancers found in the primary care setting. It is imperative that all primary care providers become competent in evaluating skin lesions. Actinic keratoses are the most common premalignant lesions. These rough scaly plaques are the direct result of ultraviolet and other carcinogenic exposure. Actinic keratoses may be the first clinical sign to alert primary care practitioners of severe solar dermatitis and herald the development of skin cancer. Treatment is cryotherapy or topical chemotherapeutic agents such as 5-fluorouracil. Basal and squamous cell carcinomas are the most common nonmelanoma skin cancers. The primary cause is cumulative exposure to ultraviolet radiation from the sun, although other factors exist. Treatment is generally surgical excision performed by a practitioner skilled in this type of procedure contingent on tumor type, size, location, aggressiveness, and other factors. Other common treatments include electrodesiccation and curettage and cryotherapy. The incidence of malignant melanoma is the fastest rising cancer in the United States. Early detection and prevention are the mainstays of a good outcome. Depth of the lesion is the primary determinant in staging and prognosis, although other factors are also important. As the incidence of skin cancer increases, primary care practitioners play an integral role in the diagnosis, treatment, and prevention of skin cancer. The importance of early detection and appropriate referral by primary care providers will become even more crucial in the prognosis of afflicted patients.
MAIN MESH HEADINGS:	Precancerous Conditions/*pathology *Skin Neoplasms
ADDITIONAL MESH HEADINGS:	Diagnosis, Differential Human Risk Factors Skin Neoplasms/diagnosis

Skin Neoplasms/epidemiology
Skin Neoplasms/etiology
Skin Neoplasms/therapy
Sunlight/adverse effects
United States/epidemiology
1999/11
1999/05 08:00

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REVIEW
REVIEW, TUTORIAL

LANGUAGES: **Eng**

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